

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE  
AT JACKSON

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WARDELL FLEMING,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 2:15-cv-02799-JPM-dkv
	)	
JANSSEN PHARMACEUTICALS, INC.,	)	
JOHNSON & JOHNSON, and MITSUBISHI	)	
TANABE PHARMA CORP.,	)	
	)	
Defendants.	)	

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ORDER GRANTING JANSSEN PHARMACEUTICALS, INC. AND  
JOHNSON & JOHNSON'S MOTION TO DISMISS

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Before the Court is Defendants Janssen Pharmaceuticals, Inc. and Johnson & Johnson's ("Defendants") Motion to Dismiss, filed February 12, 2016. (ECF No. 18). For the following reasons, Defendants' Motion to Dismiss is GRANTED. Accordingly, the Court dismisses all claims against Johnson & Johnson with prejudice; dismisses Plaintiff's design defect claims with prejudice; dismisses Plaintiff's Tennessee Consumer Protection Act ("TCPA") claims with prejudice; and dismisses Plaintiff's Tennessee Product Liability Act ("TPLA") claims without prejudice. Plaintiff is permitted to re-plead his TPLA claims with specificity within thirty (30) days of the entry of this order, up to and including July 6, 2016.

## **I. BACKGROUND**

### **A. Factual History**

Plaintiff Wardell Fleming ("Plaintiff"), a Tennessee resident, brings suit against Defendants Janssen Pharmaceuticals, Inc. ("Janssen"), a Pennsylvania corporation; Johnson & Johnson, a New Jersey corporation; and Mitsubishi Tanabe Pharma Corp. ("Tanabe"), a Japanese corporation, for injuries and damages caused by Invokana, a diabetes drug. (Compl. ¶¶ 1-3, 7-10, 18-23, ECF No. 1.) Plaintiff alleges that Defendants Tanabe and Johnson & Johnson collaborated to design and develop Invokana. (Id. ¶ 18.) Defendant Janssen, a wholly-owned subsidiary of Johnson & Johnson, acquired marketing rights to the drug in North America and marketed, advertised, distributed, and sold Invokana in states including Tennessee. (Id. ¶ 19.) Invokana was approved by the FDA for the treatment of type 2 diabetes. (Id. ¶ 21.) Invokana, an SGLT2 inhibitor, was the first drug of its kind approved by the FDA. (Id. ¶ 23.)

The FDA has since received a significant number of reports of diabetic ketoacidosis and kidney infection from Invokana users. (Id. ¶ 26.) On May 15, 2015, the FDA issued a Public Health Advisory regarding a link between SGLT2 inhibitors and diabetic ketoacidosis. (Id. ¶ 27.) Plaintiff alleges that, despite the reported adverse events, Defendants have continued to fail to warn patients about diabetic ketoacidosis as a risk

of taking Invokana. (Id. ¶¶ 28-30.) On December 4, 2015, the FDA updated Invokana's warning label to include a warning about ketoacidosis and serious urinary tract infections which can develop into kidney infections. (Id. ¶ 31.)

Plaintiff alleges that Defendants knew of the risk that severe injury could be caused by Invokana. (Id. ¶ 33.) Plaintiff began taking Invokana in or about November 2013. (Id. ¶ 35.) Plaintiff suffered kidney failure, kidney damage, and reduced kidney function after taking Invokana; in addition to physical injuries, Plaintiff also alleges emotional injuries, loss of enjoyment of life, and economic loss. (Id. ¶¶ 40, 48.) Plaintiff asserts that his injuries were a reasonably foreseeable consequence of Defendants' conduct and Invokana's defects. (Id. ¶ 43.) Plaintiff asserts he would not have used Invokana if he had been properly warned. (Id. ¶ 45.) Plaintiff asserts that there are several safer alternative products available. (Id. ¶ 32.)

## **B. Procedural History**

On December 14, 2015, Plaintiff Wardell Fleming filed a complaint against Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Mitsubishi Tanabe Pharma Corp. in the Western District of Tennessee. (ECF No. 1.) On February 12, 2016, Defendants Janssen and Johnson & Johnson ("Defendants") filed a motion to dismiss for failure to state a claim and for

lack of jurisdiction over Johnson & Johnson. (ECF No. 18.) Plaintiff responded in opposition on March 14, 2016. (ECF No. 33; see also ECF No. 31.) Defendants filed a reply on April 1, 2016. (ECF No. 36.)

The Court held a telephonic scheduling conference on March 17, 2016. (Min. Entry, ECF No. 34.) On April 6, 2016, the Court held a second scheduling conference and a hearing on the instant motion. (Min. Entry, ECF No. 38.)

On April 22, 2016, Defendant Tanabe filed a motion to dismiss. (ECF No. 42.) This motion remains pending.

## **II. LEGAL STANDARD**

### **A. Motion to Dismiss for Lack of Personal Jurisdiction**

A court may dismiss a claim for "lack of personal jurisdiction." Fed. R. Civ. P. 12(b)(2). "The plaintiff bears the burden of making a prima facie showing of the court's personal jurisdiction over the defendant." Intera Corp. v. Henderson, 428 F.3d 605, 615 (6th Cir. 2005). A plaintiff "can meet this burden by 'establishing with reasonable particularity sufficient contacts between [a defendant] and the forum state to support jurisdiction.'" Neogen Corp. v. Neo Gen Screening, Inc., 282 F.3d 883, 887 (6th Cir. 2002) (quoting Provident Nat'l Bank v. Cal. Fed. Sav. Loan Ass'n, 819 F.2d 434, 437 (3d Cir. 1987)). When the court does not conduct an evidentiary hearing on the issue, it must "not consider the facts proffered by the

defendant that conflict with those offered by the plaintiff, and will construe the facts in the light most favorable to the nonmoving party." Id. (citation omitted).

**B. Motion to Dismiss for Failure to State a Claim**

A court may dismiss a claim for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

A complaint must contain a short and plain statement of the claim showing that the pleader is entitled to relief. . . . A claim is facially plausible when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. . . . [T]he court need not accept as true allegations that are conclusory or require unwarranted inferences based on the alleged facts.

Newberry v. Silverman, 789 F.3d 636, 640 (6th Cir. 2015)

(citations and internal quotation marks omitted). "Plausibility is not the same as probability, but it requires 'more than a sheer possibility that a defendant has acted unlawfully.'" Mik v. Fed. Home Loan Mortg. Corp., 743 F.3d 149, 157 (6th Cir. 2014) (quoting Iqbal, 556 U.S. at 678). A court must "construe[] the complaint in a light most favorable to the

plaintiff." HDC, LLC v. City of Ann Arbor, 675 F.3d 608, 611 (6th Cir. 2012).

### **III. ANALYSIS**

#### **A. Personal Jurisdiction as to Johnson & Johnson**

Defendants Janssen and Johnson & Johnson assert that all claims against Johnson & Johnson should be dismissed because Plaintiff has failed to establish personal jurisdiction as to Johnson & Johnson. (ECF No. 18-1 at 4-8.) Plaintiff argues that personal jurisdiction exists because Johnson & Johnson purposefully availed itself of this Court when it designed Invokana and, along with Janssen, a subsidiary, placed Invokana in the stream of commerce in Tennessee. (ECF No. 33 at 5 (citing Daimler AG v. Bauman, 134 S. Ct. 746, 759 n.13 (2014)).) The Court finds that Johnson & Johnson does not have minimum contacts with Tennessee such that personal jurisdiction exists.

"Personal jurisdiction can be either general or specific, depending upon the nature of the contacts that the defendant has with the forum state." Bird v. Parsons, 289 F.3d 865, 873 (6th Cir. 2002). The Court examines only specific jurisdiction because Plaintiff focuses on specific jurisdiction in his response to the instant motion. (See ECF No. 33 at 3 n.1 ("Plaintiff does not claim that Johnson & Johnson is subject to general jurisdiction in Tennessee, but instead asserts specific jurisdiction.").)

To determine whether specific jurisdiction exists, the Court employs the following three-part test:

First, the defendant must purposefully avail himself of the privilege of acting in the forum state or causing a consequence in the forum state. Second, the cause of action must arise from the defendant's activities there. Finally, the acts of the defendant or consequences caused by the defendant must have a substantial enough connection with the forum state to make the exercise of jurisdiction over the defendant reasonable.

Devault-Graves Agency, LLC v. Salinger, No. 2:15-cv-02178-STA-tmp, 2015 WL 6143513, at \*4 (W.D. Tenn. Oct. 19, 2015) (quoting S. Mach. Co. v. Mohasco Indus., Inc., 401 F.2d 374, 381 (6th Cir. 1968)). In analyzing purposeful availment, the Sixth Circuit uses a "stream of commerce plus" approach that requires more than simply "[t]he placement of a product into the stream of commerce" to prove purposeful availment in the forum state. Bridgeport Music, Inc. v. Still N the Water Publ'g, 327 F.3d 472, 479-80 (6th Cir. 2003) (per curiam) (alteration in original) (internal quotation marks omitted). "The 'stream of commerce plus' test is not met when the 'defendant was "merely aware" of the fact of national distribution, but the choice to distribute was 'pretty much out of [its] hands.'" Devault-Graves, 2015 WL 6143513, at \*5 (alteration in original) (quoting Palnik v. Westlake Enter., Inc., 344 F. App'x 249, 251 (6th Cir. 2009)). Factors to consider for the "stream of commerce plus" test include "(1) the defendant's direction or

control over the flow of the product into the forum; (2) the quantity of the defendant's particular product regularly flowing into the forum; and (3) the distinctive features of the forum that connect it with the product in question." One Media IP Ltd. v. S.A.A.R. SrL, No. 3:14-cv-0957, 2015 WL 4716813, at \*8 (M.D. Tenn. Aug. 7, 2015) (citing Eaves v. Pirelli Tire, 2014 WL 1883791 (D. Kan. May 12, 2014)).

Plaintiff has not alleged facts to satisfy the "stream of commerce plus" test. First, Plaintiff has not alleged that Johnson & Johnson controlled the flow of Invokana into Tennessee. Plaintiff asserts that Johnson & Johnson "'designed and developed' Invokana in collaboration with Mitsubishi Tanabe." (ECF No. 33 at 5 (quoting Compl. ¶ 18).) Defendant asserts that Johnson & Johnson is a holding company<sup>1</sup> that "plays no role in the manufacture and sale of Invokana." (ECF No. 18-1 at 3 & n.4.) This factual dispute must be construed in the light most favorable to Plaintiff, Neogen, 282 F.3d at 887, but Plaintiff has failed to allege facts that connect the design and development of Invokana to the flow of Invokana in Tennessee.

Second, Plaintiff has not asserted a quantity of the product regularly flowing into Tennessee. Although Plaintiff

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<sup>1</sup> Other courts have found that because Johnson & Johnson is a holding company, it is not subject to specific jurisdiction where it has not availed itself of the laws of the particular state. See, e.g., Order Granting Mot. to Dismiss at 18, 33, Brazil v. Janssen Research & Dev., No. 4:15-CV-0204-HLM (N.D. Ga. Mar. 24, 2016), ECF No. 20; Androphy v. Smith & Nephew, Inc., 31 F. Supp. 2d 620, 622 (N.D. Ill. 1998).



asserts that Johnson & Johnson has derived a substantial amount of revenue from Tennessee because Johnson & Johnson reported \$890 million in U.S. sales of Invokana in the first nine months of 2015 alone (ECF No. 33 at 4 & n.2), Plaintiff fails to specify the sales related to Tennessee. Third, Plaintiff has failed to connect any distinctive features of Tennessee to Invokana. The record does not indicate that Johnson & Johnson has purposefully availed itself of the laws of Tennessee, and thus, the first part of the specific jurisdiction test is not met.<sup>2</sup>

The Court, therefore, need not reach the second and third parts of the specific jurisdiction test. Even if the first part were satisfied, Plaintiff has not satisfied the second by showing that Johnson & Johnson's actions in Tennessee caused the injuries he asserts. The record does not indicate that Johnson & Johnson acted in Tennessee to cause Plaintiff's alleged injury. While Plaintiff asserts that he was prescribed, purchased, and used Invokana in Tennessee (Compl. ¶ 7), Plaintiff's own actions in the forum state are not sufficient to establish specific jurisdiction. See Devault-Graves, 2015 WL

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<sup>2</sup> While there is case law to support Plaintiff's argument that Johnson & Johnson's nationwide sales and marketing activities indicate that Johnson & Johnson has minimum contacts with Tennessee, see, e.g., In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig., MDL Docket No. 3:11-MD-2244-K, 2014 WL 3557392 at \*2 (N.D. Tex. July 18, 2014), the Sixth Circuit standard of "stream of commerce plus" is controlling in the instant case.

6143513, at \*6. Although the third part might be satisfied<sup>3</sup> when considering the factors of burden to Defendants and Plaintiff's interest, id., it alone cannot establish specific jurisdiction.

Accordingly, because specific jurisdiction cannot be established over Johnson & Johnson, the Court GRANTS Defendants' motion to dismiss Plaintiff's claims against Johnson & Johnson.

#### **B. Preemption of Design Defect Claims**

Defendants assert that Plaintiff's design defect claims (Counts I and IX), which are premised on the proposition that Defendants should have designed Invokana differently, are preempted by federal law. (ECF No. 18-1 at 15.) Plaintiff argues that a case Defendants rely on, Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013), is distinguishable because it applied to generic drugs, not branded drugs like Invokana. (ECF No. 33 at 6-10.) Plaintiff also asserts that the focus of his claims is on design defects before FDA approval, not Defendants' failure to redesign after FDA approval. (Id. at 8.) The Court finds that Plaintiff's design defect claims are preempted based on Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc., 808 F.3d 281 (6th Cir. 2015), and

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<sup>3</sup> Plaintiff must show that "Tennessee has an interest in resolving the conflict such that jurisdiction over the defendant is reasonable." Devault-Graves, 2015 WL 6143513, at \*6 (citing Mohasco, 401 F.2d at 384). Plaintiff is a Tennessee resident (Compl. ¶ 7), which suggests that the state has an interest in resolving the conflict in Tennessee; and Johnson & Johnson would likely not face a significant burden by litigating in Tennessee.

therefore grants Defendants' motion to dismiss the design defect claims.

Several Supreme Court cases provide guidance as to whether the design defect claims are impossible as a matter of law: Wyeth v. Levine, 555 U.S. 555 (2009), PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011), and Bartlett. In Levine, the Supreme Court held that state claims were not preempted when Wyeth, a drug manufacturer, could comply with both state and federal law obligations. 555 U.S. at 581. In that case, the Court found that the FDA's 2006 preamble which Wyeth relied on was contrary to "the FDA's own longstanding position" of recognizing state law remedies. Id. at 577, 580-81. In Mensing, by contrast, the Supreme Court found impossibility when generic drug manufacturers could not comply with state-law duties to provide adequate warning labels because federal statutes and regulations required the manufacturers to use the same labeling as the drug's branded counterparts. 564 U.S. at 610-11. The state claims were thus preempted. Similarly, citing Mensing, the Supreme Court found in Bartlett that state-law design defects claims were preempted by federal law preventing generic drug manufacturers from changing the chemistry of their drugs or changing the labels of their drugs. 133 S. Ct. at 2475-76.

Under Tennessee law,

[w]arnings concerning prescription drugs generally are adequate when they contain a full and complete disclosure of the potential adverse reactions to the drug. A reasonable warning not only conveys a fair indication of the dangers involved, but also warns with the degree of intensity required by the nature of the risk.

Pittman v. Upjohn Co., 890 S.W.2d 425, 428-29 (Tenn. 1994).

"Tennessee law thus appears to track the laws of Louisiana and Minnesota discussed in Mensing, which impose a similar duty on the manufacturer to warn of known dangers associated with its product." Strayhorn v. Wyeth Pharms., Inc., 737 F.3d 378, 393 (6th Cir. 2013).

The Sixth Circuit clarified that impossibility preemption is not limited to generic drugs. Yates, 808 F.3d at 296. Accordingly, in Yates, the design defect claims against the manufacturers of a branded product were preempted. Id. at 293-300.

Defendants argue that it would have been impossible for Janssen to redesign Invokana under state law without violating federal law prohibiting such a design change without prior FDA approval. (ECF No. 18-1 at 19-20.) Plaintiff argues that the issue is not Defendants' duty to redesign the warning label after FDA approval but rather Defendants' duty to design the drug differently before FDA approval. (ECF No. 33 at 9-10.) The Sixth Circuit, however, found this type of argument to be

"too attenuated" and "speculat[ive]" because it requires several assumptions as to FDA approval and a patient's selection of and medical reaction to the alternative design. Yates, 808 F.3d at 299-300 ("Defendants could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's approval prior to marketing [the branded drug], and certainly prior to [plaintiff's] use of the drug.") The Court finds that in the instant case, Defendants could not comply with both state law and federal law with regard to Invokana.

Other district courts have also determined that claims against branded drugs are subject to preemption. See, e.g., Batoh v. McNeil-PPC, Inc., --- F. Supp. 3d ---, No. 3:14-cv-01462 (MPS), 2016 WL 922779 (D. Conn. Mar. 10, 2016), appeals docketed, No. 16-1060 (2d Cir. Apr. 7, 2016), No. 16-1288 (2d Cir. Apr. 25, 2016). But see, e.g., Order Granting Mot. to Dismiss at 79-82, Brazil, No. 4:15-CV-0204-HLM (discounting the persuasiveness of Yates and finding in another Invokana case that the plaintiff's design defect claims were not preempted). Unlike in Brazil in the Northern District of Georgia, Yates is controlling authority in the instant case. The Court finds that Plaintiff's design defect claims are preempted by federal law because preemption can apply to both generic and branded drugs and because it would have been impossible for Defendants to comply with both state and federal

law. Thus, Defendants' motion to dismiss is GRANTED as to the design defect claims.

**C. Damages Under the Tennessee Consumer Protection Act ("TCPA")**

Defendants assert that Plaintiff cannot recover damages under the Tennessee Consumer Protection Act ("TCPA") because he "has failed to allege an ascertainable loss of money or property as required under the statute." (ECF No. 18-1 at 8.) Plaintiff argues that he suffered economic damages from purchasing Invokana. (ECF No. 33 at 10.) Plaintiff asserts that his economic damages are "separate and distinct" from damages resulting from his personal injury. (Id.) The Court disagrees and finds that Plaintiff has failed to state a claim under the TCPA.

The TCPA allows for recovery by "[a]ny person who suffers an ascertainable loss of money . . . or thing of value wherever situated, as a result of the use or employment by another person of an unfair or deceptive act or practice described in § 47-18-104(b) and declared to be unlawful by this part." Tenn. Code Ann. § 47-18-109(a)(1). The alleged "consumer injury must be more than trivial or speculative." Waggin' Train, LLC v. Normerica, Inc., No. 1:09-cv-01093, 2010 WL 145776, at \*4 (W.D. Tenn. Jan. 8, 2010) (quoting Tucker v. Sierra Builders, 180 S.W.3d 109, 117 (Tenn. Ct. App. 2005)). "A TCPA claim must be

dismissed where a plaintiff 'seeks to recover for injuries to his person resulting from [a defendant's] alleged violation of the TCPA.'" Riddle v. Lowe's Home Ctrs., Inc., 802 F. Supp. 2d 900, 909 (M.D. Tenn. 2011) (quoting Birdsong v. Eli Lilly & Co., No. 3:10-01182, 2011 WL 1259650, at \*3 (M.D. Tenn. Mar. 31, 2011)).

Plaintiff argues that the economic damages he suffered due to Defendants' violation of the TCPA are based on "the purchase price of the drug that he would not have purchased but for Defendants' wrongful conduct." (ECF No. 33 at 10 (citing Compl. ¶¶ 89, 200).) These damages are speculative, however, since there is nothing in the record that indicates Plaintiff's expenditures from purchasing Invokana.

Further, the record does not support Plaintiff's assertion that the economic damages are "separate and distinct" from his personal injury. The "medical and related expenses" Plaintiff asserts are directly related to the alleged injuries suffered after using Invokana. (Compl. ¶ 227.) Plaintiff also suggests that his economic damages could have been avoided if he had not been injured by Defendants' alleged TCPA violation. (See, e.g., Compl. ¶¶ 89-91.) The asserted damages, therefore, do not "exist[] independently of the personal injuries that he suffered." Riddle, 802 F. Supp. 2d at 909.

Because Plaintiff has failed to state a claim under the TCPA, Defendants' motion to dismiss is GRANTED as to Plaintiff's TCPA claims.

**D. Sufficiency of Pleading Under the Tennessee Product Liability Act ("TPLA")**

Defendants assert that Plaintiff provides only conclusory allegations about the defectiveness or dangerousness of Invokana and thus fails to state a claim under the Tennessee Product Liability Act ("TPLA"). (ECF No. 18-1 at 10-11.) Plaintiff argues that he has sufficiently stated a claim for design defects (Counts I and IX) under the TPLA because he has alleged that Invokana's design causes excess glucose excretion by the kidneys (Compl. ¶ 24) and because the FDA issued an advisory regarding Invokana and ketoacidosis and later required a change in the labeling of Invokana (id. ¶¶ 27, 31). (ECF No. 33 at 13.) The Court finds that Plaintiff fails to state a claim under the TPLA and must re-plead with specificity any TPLA claims he wishes to pursue.

The TPLA states that: "A manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." Tenn. Code Ann. § 29-28-105(a). "[U]nder Tennessee law, establishing



a prima facie products-liability claim requires that the plaintiff must show: (1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product." Sigler v. Am. Honda Motor Co., 532 F.3d 469, 483 (6th Cir. 2008) (internal quotations marks omitted). As to unreasonable dangerousness, a plaintiff can demonstrate either that the product's performance did not meet consumer expectations or that the manufacturer was not prudent. Id. at 483-84 & n.6.

A plaintiff must, at the pleading stage, allege facts that indicate how the alleged defect(s) caused his injuries. Brewer v. Mr. Heater, Inc., No. 13-1330, 2014 WL 1364825, at \*2 (W.D. Tenn. Apr. 7, 2014). The complaint in Brewer was dismissed because the facts set forth were, save for one allegation describing an insufficient component of the allegedly defective device, "nothing but 'labels and conclusions' or 'formulaic recitation[s] of the elements' of various causes of action." Id. at \*3 (alteration in original) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

Similarly, in the instant case, Plaintiff's complaint consists largely of legal conclusions, and the Court cannot make a reasonable inference of Defendants' liability from the facts alleged. The only assertion as to how the product design was

defective is a description of how the class of products works. (See Compl. ¶ 24 ("SGLT2 inhibitors . . . are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease.").) The Court cannot reasonably infer from the generic description of SGLT2 inhibitors' mechanism of action that Invokana was defective or unreasonably dangerous.

The facts are also insufficient as to the alleged defect as the cause of Plaintiff's injuries. Plaintiff asserts, for example, that "[a]s a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of INVOKANA, Plaintiff suffered severe and permanent physical and emotional injuries." (Compl. ¶ 48.) Under Rule 12(b)(6), such "unadorned, the-defendant-unlawfully-harmed-me accusation[s]" are insufficient to state a claim.

Iqbal, 556 U.S. at 678.

Plaintiff's claims for warning defects also fail for similar reasons. "To plead a 'failure to warn' claim, Plaintiff must allege facts for the Court to infer that the Device was 'unreasonably dangerous' within the meaning of T.C.A. § 29-28-102(8)." Maness v. Boston Sci., 751 F. Supp. 2d 962, 970 (E.D. Tenn. 2010) (footnote omitted). Plaintiff has made only

conclusory statements as to the failure of Defendants to warn about the dangers of Invokana. (See, e.g., Compl. ¶ 76 (“INVOKANA contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with INVOKANA, including the development of Plaintiff’s injuries.”).)

Plaintiff’s other claims for breach of warranties, misrepresentation, concealment, and fraud are encompassed within the scope of actions under the TPLA. See Tilden v. Gen. Elec. Co., No. 3:11-CV-628, 2012 WL 1023617, at \*2 & n.4 (E.D. Tenn. Mar. 26, 2012) (citing Tenn. Code Ann. § 29-28-102(6)). Because Plaintiff has not stated a sufficient claim under the TPLA for product liability, all remaining claims must be dismissed. See Tenn. Code Ann. § 29-28-102(6); see also Strayhorn, 882 F. Supp. 2d at 1028.

Accordingly, the Court GRANTS Defendants’ Motion to Dismiss on the ground of failure to state a claim under the TPLA. Plaintiff’s TPLA claims are dismissed without prejudice, and Plaintiff is permitted to re-plead these claims with specificity within thirty days.

#### **IV. CONCLUSION**

For the reasons stated above, Defendants’ Motion to Dismiss is GRANTED. Plaintiff is permitted to re-plead with specificity

any claims dismissed without prejudice within thirty days, up to and including July 6, 2016.

**IT IS SO ORDERED**, this 6th day of June, 2016.

/s/ Jon P. McCalla  
JON P. McCALLA  
UNITED STATES DISTRICT JUDGE